PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

ASACOL®
400 mg
Enteric-coated Tablets

Active ingredient:
Mesalazine (5-Aminosalicylic Acid) 400 mg/tablet

ASACOL®
800 mg
Enteric-coated Tablets

Active ingredient:
Mesalazine (5-Aminosalicylic Acid) 800 mg/tablet

Inactive ingredients:
See section 6 – Further information

Each tablet of 400 mg contains 76.40 mg lactose
Each tablet of 800 mg contains 152.80 mg lactose

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is intended for the treatment of ulcerative colitis and Crohn's disease.

Therapeutic group:
Amino salicylates

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine:
- If you are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medicine (listed in section 6 – Further information) or to salicylates, such as aspirin.
- Do not use in patients with severe liver and kidney impairment (glomerular filtration rate [GFR] less than 20 ml per minute).
- Other contra-indications include gastric or duodenal ulcers, hemorrhagic tendency, children under two years of age.

Special warnings regarding the use of this medicine
Before beginning treatment with Asacol, tell the doctor if:
- you have any lung problems, e.g. asthma
- you have suffered in the past from an allergy to sulphasalazine
- you have ever had heart problems such as inflammation of the heart muscle or heart sac. If you have had heart problems in the past suspected to be caused by mesalazine; in such a case, Asacol must not be taken. Asacol can be taken with care if you have had a previous heart problem not caused by mesalazine.
- if you have a gastric or intestinal ulcer

There have been reports of very rare incidents of severe disorders of the blood composition (blood dyscrasia). Hematological tests, including a complete blood count, should be performed before starting the treatment, as well as during the course of treatment, at the discretion of the attending doctor. It is usually recommended that these tests be performed within two weeks of starting treatment and be repeated 2-3 times every 4 weeks.
If these tests are normal, it is recommended that they be repeated once in three months. If additional signs of disease show up, additional tests should be performed, as necessary.
This procedure should be performed especially if signs or symptoms that raise suspicions of blood dyscrasia, such as unexplained bleeding, hematomas, purpura, anemia, prolonged fever, or sore throat, develop during the course of treatment. If suspicion of blood dyscrasia arises, or if there is evidence of such a disorder, stop treatment with Asacol immediately and seek medical attention immediately.

The safety and effectiveness of Asacol tablets in children has not been fully established.

Use in the elderly must be with caution, and is only suitable for patients with normal kidney function.

❗If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:
- Azathioprine, 6-mercaptopurine and thioguanine – mesalazine can increase the immunosuppressive effect.
  Blood parameters, especially the leukocyte, thrombocyte and lymphocyte cell counts should be monitored regularly (weekly), especially at initiation of such combination therapy. If the white blood cell count is stable after one month, testing every 4 weeks for the following 12 weeks followed by 3 monthly monitoring intervals appears to be justified.
- Warfarin - mesalazine can decrease the anticoagulant effect.

❗Use of medicine and food
The medicine should be taken before meals.

❗Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult with a doctor or pharmacist before using this medicine.

❗Driving and using machinery
This medicine has no or negligible influence on the ability to drive and use machines.
However, if you are affected in any way, do not drive or operate machinery.

❗This medicine contains milk sugar (lactose)
Patients who are intolerant to lactose should know that this medicine contains a small amount of lactose.
If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Allow a lapse of at least two hours between taking this medicine and taking antacids.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and manner of treatment will be determined by the doctor only.

The standard dosage is
Ulcerative colitis: 1.2 to 2.4 grams per day in divided doses.
Crohn's disease: 2.4 grams in divided doses.

Do not exceed the recommended dosage.

This medicine should be taken before meals and must be swallowed whole, preferably with some liquid. Do not chew, crush or break the tablets before swallowing them. Do not retain this medicine in the mouth for a period longer than that required for swallowing it.

Tests and Follow-up
Before beginning use of this medicine and during treatment, your doctor may want to monitor from time to time, to check that your liver, kidneys, blood and lungs are all right.
There have been a few reports of intact tablets in the stool. What appear to be an intact tablet may sometimes be the remains of the tablet coating. If you often observe tablets or tablet shells in the stool, you should consult the doctor.

If you accidentally take a higher dosage
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine
If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult the doctor.

If you stop taking the medicine
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

How can you contribute to the success of the treatment
Complete the full course of treatment as instructed by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

4. SIDE EFFECTS

As with any medicine, use of Asacol may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.
Evaluation of the side effects is based on the following frequencies:
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Unknown frequency: the frequency can not be estimated from the existing data

Organ-specific side effects affecting the heart, lungs, liver, kidneys, pancreas, skin and subcutaneous tissue have been reported.

Stop taking the medicine immediately and contact the doctor immediately
If you develop unexplained bruising (without injury), bleeding under your skin, purple spots or patches under your skin, anaemia (feeling tired, weak and looking pale, especially on lips, nails and inside of eyelids), high fever, sore throat or unusual bleeding (e.g., nose bleeds).

The following side effects have been reported at the approximate frequencies shown:

Common
- rash
- indigestion

Uncommon
- fever
- high number of white blood cells called eosinophil granulocytes
- sensation of tingling, pricking and numbness
- hives, itching skin
- chest pain

Rare
- headache
- dizziness
- inflammation of the heart with signs like chest pains or palpitations
- diarrhoea, stomach pain, wind (flatulence), feeling of unease and discomfort in the stomach with an urge to vomit and vomiting.

Very rare
- severe reduction in blood cell counts which can cause weakness, bruising or make infections more likely, low blood cell counts; reduction in blood platelets which increases the risk of bleeding
- allergic reactions such as rash or skin eruption
- fever that occurs while taking the medicine and disappears when the medicine is stopped (drug fever)
- immune system disease that can involve organs and joints
- ulcerative colitis involving the entire large intestine
- abnormal or damaged nerves giving a sensation of numbness or tingling
- lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing or wheezing and collection of fluid in the lungs, pneumonia
- inflamed pancreas associated with pain in upper abdomen and back and nausea
- abnormal liver function tests, hepatitis (inflammation of the liver giving rise to flu-like symptoms and jaundice)
- hair loss
- muscle and joint pain
- kidney problems (such as inflammation and scarring of the kidney), kidney failure, which may be reversible if treatment is stopped early
- reversible decrease in sperm production

Unknown frequency
- disorder of the immune system (lupus-like syndrome) which can cause inflammation of the heart sac or of membranes around the lungs and heart, rash and/or joint pain
- weight loss
- laboratory test results out of normal range.

If a side effect appeared, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, you must consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicines, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
Do not store at a temperature above 25°C. Keep the tablets in the original package to protect them from moisture.

6. FURTHER INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
  lactose monohydrate
  sodium starch glycolate (type A)
  magnesium stearate
  talc micronized
  povidone
  methacrylic acid-methyl methacrylate copolymer (1:2)
  triethyl citrate
  ferric oxide red and yellow (E172)
  macrogol 6000
- **What the medicine looks like and the contents of the package**
  Coated, reddish to brownish oblong tablets with a glossy to matte finish. The tablets come in blisters (trays) of 10 tablets, which are packed as:
  Asacol 400 mg: 100 tablets per package
  Asacol 800 mg: 60 tablets per package

License holder and importer: Tradis Gat Ltd., P.O.B. 7775, Petach Tikvah 49170.

Manufacturer: Tillotts Pharma, Switzerland.

This leaflet was checked and approved by the Ministry of Health in: December 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Asacol 400 mg - 659925654
Asacol 800 mg - 1333931029